REMARKS

The Office Action of January 14, 2005, has been received and reviewed. Claims 1, 2, 4-12 and 14-28 are pending in the application of which claims 4-10, 12, 14, 15, 18, 19 and 25-28 have been withdrawn from consideration as being directed to a non-elected invention. Claims 21 and 22 are allowed, and claims 1, 2, 11, 16, 17, 20, 23 and 24 stand rejected. Claims 1-2, 11, 20 and 24 have been amended and claims 16 and 17 have been canceled as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-2, 11, 16-17, 20 and 23-34 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bilej et al. (Eur. Cytokine Network, Vol. 5, No. 2, 1994) and Bilej et al. (Immunology Letters, 45, 1995). Claims 16 and 17 have been canceled rendering the rejections thereof moot. Applicants traverse the remaining rejections as set forth herein.

Specifically, the Office Action asserted that "there is nothing on the record to show why the peptide of the reference is not the same as the claimed peptide" and that the "purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art." (Office Action, page 4; *see also*, *Id.* at page 6).

However, the Federal Circuit has indicated that claiming a compound in "its pure and isolated form" is one way to avoid anticipation. (*Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664, 1670-71 (Fed. Cir. 2003), *citing In re Kratz*, 592 F.2d 1169, 1174, 201 USPQ 71 (CCPA 1979) and *In re Bergstrom*, 427 F.2d 1394, 1401-02, 166 USPQ 256 (CCPA 1970)). The Federal Circuit indicated that *In re Kratz* stands for the proposition "that a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound" and that *In re Bergstrom* states "that a material occurring in nature in less pure form does not anticipate claims to the pure material." (*Id.*)

Thus, the statement in the Office Action that the purification or production of a product by a particular process does not impart novelty (*see*, Office Action at pages 4 and 6) is not in accordance with the law as established by the Federal Circuit. Accordingly, since Bilej et al.

indicates that "a **semi-pure** fraction was used to prepare monoclonal antibodies (mAb) that were screened for neutralizing the cytolytic effects of the coelomic fluid," (Bilej et al., Euro. Cytokine Network, Abstract) (*emphasis added*) Bilej et al. does not disclose any **isolated** protein.

With regards to the other Bilej et al. reference (*i.e.*, in Immunology Letters), it discloses

> *3.4* ***Semi-purification*** *of the cytolytic fractions of the coelemic fluid*
> Three-times diluted CF sample (3.3 mg/ml) was dialyzed for 3 h in 100 mM TRIS + 1 mM EDTA buffer (pH 8) at 4°C and subjected to ion-exchange chromatography ... dialyzed and concentrated tumoricidal fractions obtained from ion-exchange chromatography was used for intra-food pad immunization of Balb/c mice.

(Bilej et al., Immunology Letters at page 124) (*emphasis added*). Thus, since the Bilej et al. references do not disclose any **isolated** proteins, they cannot anticipate any of the claims reciting an isolated protein.

The Federal Circuit further noted the importance of isolated or pure compounds in regard to a sequence of a molecule. In discussing the novelty of a gene (which is known in the art to code for a protein), the Federal Circuit indicated "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." (*Amgen Inc. v. Chugai Pharmaceutical Col., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ 2d 1016 (Fed. Cir.1991), *rehearing In Banc declined*). The Federal Circuit further stated that

> until [the inventor] had a complete mental conception of a **purified and isolated** DNA sequence encoding EPO and a method for its preparation, in which the precise identity of the sequence is envisioned, or in terms of other characteristics sufficient to distinguish it from other genes, all he had was an objective to make an invention which he could not then adequately describe or define.

(*Id.*) (*emphasis added*). Thus, since the proteins of the Bilej et al. references are not pure or isolated, they cannot disclose a specific sequence. Accordingly, the Bilej et al. references cannot anticipate the isolated proteins identified by a specific sequence (*i.e.*, SEQ ID NO: 1 or 3) as recited in the pending claims.

With further regard to amended claim 1, it is directed towards an isolated peptide which has from 13 to **no more than** 60 amino acids, and which comprises SEQ ID NO: 1, wherein the

isolated peptide possesses trypanolytic activity as determined by a trypanolytic assay. Neither of the Bilej et al. references can anticipate amended claim 1 since they do not disclose an isolated peptide which has no more than 60 amino acids in length. Rather, the Bilej et al. references disclose **full-length** proteins and not proteins that are no more than 60 amino acids in length. (*See generally*, Bilej et al., Immunology Letters and European Cytokine Network).

Accordingly, claims 1, 2, 20, 23 and 24 directed towards an **isolated** peptide, and the composition claims 11, 16 and 17 including an **isolated** peptide are novel over the Bilej et al. references.

Reconsideration and withdrawal of the anticipation rejections of claims 1-2, 11, 20 and 23-34 are requested.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 1-2, 11, 16-17, 20 and 23-24 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking compliance with the written description requirement. Claims 16 and 17 have been canceled rendering the rejections thereof moot. Applicants traverse the remaining rejections as set forth herein.

Specifically, it was thought that the specification broadly describes a genus of isolated peptides that have no structural description accompanying the variant language recited in the claims and that the specification has failed to describe the structure of the claimed fragments or epitopes of SEQ ID NO: 1 and SEQ ID NO: 3. (*See*, Office Action at pages 7 and 8).

The MPEP indicates that written description may be shown by "describing the claimed invention with all of its limitations using such descriptive means as words, structures ... [and] by describing distinguishing identifying characteristics sufficient to show that the applicants were in possession of the claimed invention." (M.P.E.P. § 2163, page 2100-165). Thus, one of ordinary skill in the art would conclude that since the isolated peptide of claim 1 is described with a structure (*i.e.*, an isolated peptide which has from 13 to no more than 60 amino acids and which comprises SEQ ID NO: 1) and an identifying characteristic (*i.e.*, the function of possessing trypanolytic activity), the written description exists for amended claim 1.

Further, amended claim 3 is directed towards an isolated or recombinant peptide having a structure (*i.e.*, comprising the amino acid sequence of SEQ ID NO: 3 or a fragment thereof comprising SEQ ID NO: 1), wherein the isolated or recombinant peptide or the fragment thereof has an identifying characteristic (*i.e.*, by possessing trypanolytic activity).

Further, the composition of amended claim 11 is directed towards a structure (*i.e*, an isolated peptide having from 13 to no more than 60 amino acids that comprises SEQ ID NO: 1, an isolated or recombinant peptide comprising SEQ ID NO: 3, or a fragment of SEQ ID NO: 3 comprising SEQ ID NO: 1) having an identifying characteristic (*i.e.*, wherein each of the peptides of amended claim 11 possess trypanolytic activity).

Similarly, the isolated or recombinant peptide of amended claim 20 is directed towards a structure (*i.e.*, SEQ ID NO: 1, an amino acid sequence which has from 13 to no more than 60 amino acids and which comprises SEQ ID NO: 1, a recombinant amino acid sequence comprising SEQ ID NO: 3, and a fragment of the recombinant amino acid sequence comprising SEQ ID NO: 1) that has an identifying characteristic (*i.e.*, possessing trypanolytic activity).

With regards to claim 23, it also is directed towards a structure (*i.e.*, an isolated peptide consisting essentially of SEQ ID NO: 1) having an identifying characteristic (*i.e.*, trypanolytic activity). Claims 24 is directed towards a structure (*i.e.*, an isolated or recombinant peptide consisting essentially of SEQ ID NO: 3 or a fragment thereof comprising SEQ ID NO: 1) and an identifying characteristic (*i.e.*, trypanolytic activity).

Since the as-filed specification describes peptides that contain SEQ ID NO: 1, that SEQ ID NO: 1 has trypanolytic activity, and fragments of SEQ ID NO: 3 that vary in length and include SEQ ID NO: 1 that possess trypanolytic activity, (*see*, Specification as-filed, pages 3-4 and 9-10), one of ordinary skill in the art would conclude that the inventors were in possession of claims 1-2, 11, 16-17, 20 and 23-24.

Thus, reconsideration and withdrawal of the written description rejections of claims 1-2, 11, 20 and 23-24 are requested.

Enablement

Claims 1-2, 11, 16-17, 20 and 23-24 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which would not enable one skilled in the art

to make or use the claimed invention. Claims 16 and 17 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein. (*See*, Office Action at page 9).

The Office Action stated that the specification has failed to describe the structure of the claimed fragments or epitopes of SEQ ID NO: 1 and SEQ ID NO: 3, and that the applicants have not disclosed a representative amount of species within the claimed genus to enable the genus of peptides encompassed by the claims. (*See*, *Id.* at pages 11-12).

However, the specification discloses a trypanolytic domain of CCF-1 to be SEQ ID NO: 1. (*See*, Specification as-filed page 17). The specification further teaches that recombinantly produced CCF-1 (*e.g.*, rCCF-1 which comprises SEQ ID NO: 3) is trypanolytic. (*See*, *Id.* at page 21). rCCF-1 was produced by expressing a nucleic acid that encoded rCCF-1. (*See*, *Id.* at pages 20-21). The specification further discloses that

> polypeptides may be generated in any manner, including for example, chemical synthesis, or expression of a recombinant expression system, or isolation form a suitable viral system... it is also understood that the proteins according to the present invention may be further modified by conventional methods known in the art. By providing the proteins according to the present invention, it is also possible to determine fragments which retain biological activity.

(*Id.* at page 9). Thus, one of ordinary skill in the art would be able to make and use peptides that are fragments of SEQ ID NO: 3, that include SEQ ID NO: 1 and that possess trypanolytic activity without undue experimentation.

Further, the previously submitted Declaration of Dr. Alain Beschin indicates that fragments of SEQ ID NO: 3 and that include SEQ ID NO: 1 possess trypanolytic activity. For instance, the Declaration indicates that peptide fragments E3 and E4, each of which include SEQ ID NO: 1 and each of which are fragments of SEQ ID NO: 3, possess trypanolytic activity as determined by a trypanolytic assay commensurate in scope with the as-filed specification. (*See*, Specification as-filed, pages 14-15). Accordingly, one of ordinary skill in the art would be able to make and use the isolated peptides and compositions of the instant invention without undue experimentation.

The Office Action also asserted that "Applicant's instant specification teaches that the *Eisenia* polypeptides and recombinant polypeptides of the invention are useful in tumor therapy,

microbial infection, inflammation or immunology" and that "one of skill in the art would require undue experimentation to determine whether the claimed pharmaceutical compositions can be used to protect against any microbial infection or diseases or cancer." (Office Action at pages 15-16) (emphasis added). Applicants request clarification of the instant rejection since it appears to be a utility rejection, however, no rejection under 35 U.S.C. § 101 has been made. (*See*, M.P.E.P. § 2164.07).

Further, as stated in the MPEP "[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an 'immediate benefit to the public' and thus satisfies the utility requirement." (M.P.E.P. § 2107.01 (III)). "Office personnel should also be especially careful not to read into a claim **unclaimed** results, limitations or embodiments of an invention." (*Id.* at 2107.02 (I)). Thus, as the isolated peptide and composition elements of the pending claims do not include language that asserts protection against any microbial infection or diseases or cancer as asserted in the Office Action, the identification of a pharmacological activity (*i.e.*, trypanolytic activity) in the as-filed specification of the isolated peptides or compositions has been established. Thus, since the as-filed specification indicates that the isolated peptides and compositions are shown to exhibit trypanolytic activity (*See*, Specification as-filed at pages 21-22), the utility of 35 U.S.C. § 112, first paragraph, is satisfied.

Reconsideration and withdrawal of the enablement rejections of claims 1-2, 11, 20 and 23-24 are requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 11, 16-17 and 20 also stand rejected under 35 U.S.C. § 112, second paragraph, for assertedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16 and 17 have been canceled rendering the rejections thereof moot. Applicants traverse the rejections as set forth herein.

It was thought to be unclear as to what the applicants are referring since claim 1 recites from 13 to 60 amino acids, while SEQ ID NO: 1 is 13 amino acids in length. (*See*, Office Action at page 16). Although applicants do not agree with the indefiniteness rejections, to expedite prosecution, claim 1 has been amended to recite in part an isolated peptide which has from 13 to

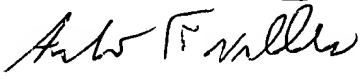
no more than 60 amino acids. Thus, amended claim 1 is directed towards an isolated peptide that is between 13 and 60 amino acids in length, wherein the isolated peptide includes SEQ ID NO: 1.

Reconsideration and withdrawal of the indefiniteness rejections of claims 1, 11, and 20 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, the applicants submit that the claims define patentable subject matter and a notice of allowance is requested. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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